Application No. 10/539,627 Attorney Docket No. P70650US0

Ferkol SEQ ID NO: 31 is the 28-amino-acid-containing sequence

CFLEAIPMSIPPEVKFNKPFVFLIIHRD.

The statement of restriction provides no explanation, whatsoever, as to how the 28-amino-acid containing sequence of Ferkol SEQ ID NO: 31 constitutes a disclosure of the 20-amino-acidcontaining segment corresponding to "residues 3-22" of Ferkol SEQ ID NO: 31.

Ferkol SEQ ID NO: 31 discloses neither more nor less than the chain of 28 amino acids, which it represents. On the other hand, given the conclusion reached in the statement of restriction, Ferkol SEQ ID NO: 31 constitutes a disclosure of every peptide (i.e., amino acid fragment) corresponding to two or more consecutive amino acids found in Ferkol SEQ ID NO: 31 (e.g., each of residues 3-22, residues 4-22, residues 5-22, residues 6-22, residues 7-22, residues 8-22, residues 9-22, residues 10-22, residues 11-22, residues 12-22, residues 13-22, residues 14-22, residues 15-22, residues 16-22, residues 17-22, residues 18-22, residues 19-20, and residues 21-22).

In making a restriction requirement "Examiners must provide reasons and/or examples to support conclusions." MPEP 803(II) (emphasis added). Lack of patentable contribution over the prior art

cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion.

In re Kahn, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

Finding no contribution over the prior art constitutes a "mere conclusory statement," there being no "articulated reasoning with some rational underpinning to support the legal conclusion" and, as such, the finding—and the requirement for restriction relying thereon—"cannot be sustained." Kahn, 78 USPQ2d at 1336. The failure "to support conclusions"—by providing the requisite "reasons and/or examples"—renders the restriction untenable. MPEP 803(II). Withdrawal of the restriction requirement appears to be in order.

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Restriction among invention Groups I-IV is further traversed, since it violates PCT Rule 13.1. In accordance with MPEP Appendix AI (Administrative Instructions under the PCT, Annex B, Part I [Instructions Concerning Unity of Invention]):

(c) Independent and Dependent Claims.

Unity of invention has to be considered in the first place only in relation to the independent claims . . . If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims.

Present claims 2-21 are all dependent (directly or indirectly) on present independent claim 132. Since the statement of restriction fails to show lack of unity of invention with respect to independent claim 132, as explained above, restriction involving any of dependent claims 133-144 is prohibited, *per se.* MPEP Annex AI.

Restriction among species SEQ ID NOS: 2-28 is traversed as it violates PCT Rule 13.1. In accordance with MPEP Appendix AI:

(c) Independent and Dependent Claims.

Unity of invention has to be considered in the first place only in relation to the independent claims... If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims.... Equally, no problem arises in the case of a genus/species situation where the genus claim avoids the prior art. (emphasis added).

Since present "genus claim [1] avoids the prior art," as explained above, and "a genus/species situation" exists between the generic peptide in (independent) claim 1 and each of the SEQ ID NOS: 2-28 peptides (in dependent claims), it is improper, *per se*, to require restriction among the SEQ ID NOS: 2-28 peptide species. MPEP Appendix AI.

Furthermore, restriction among species SEQ ID NOS: 2-28 is improper because a claim cannot be subject to restriction under §121 merely because allegedly independent and distinct inventions fall within the generic scope of the claim. *In re Weber*, 198 USPQ 328-332 (CCPA 1978). *In re Haas* ("Haas I"), 179 USPQ 623 (CCPA 1973). *See* also MPEP 803.02.

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Favorable action is requested.

Respectfully submitted,

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